FTS-COMMERCE

Moderator: Paul A. Pavwoski
August 22, 2006
12:30 pm CT

Coordinator: Good afternoon and thank you for standing by.

All participants will be on a listen-only until the question and answer portion of today's conference.

To ask a question, you press star-1. You will be prompted to record your first and last name.

Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the conference over to Mr. Paul Pavwoski.

Sir, you may begin.

((Crosstalk))

Woman: Hi, everyone. We're just waiting to get started here. We have everything okay with our technology, but we're just waiting for everybody to get organized and seated and we'll begin momentarily.

((Crosstalk))

Woman: (Dr. Dornado).

(Dornado): Hello.

Woman: Good afternoon.

(Dornado): Good afternoon.

Woman: Are you okay with the agenda that I sent you over earlier this afternoon?

(Dornado): Yeah, yeah.

Woman: Okay.

(Dornado): Okay, (unintelligible).

Woman: Okay. Are you all set there?

Woman: Yeah.

(Dornado): Yup.

Man: Yes, yes.

Woman: Okay, great. Well then I'm just going to turn everything over to my supervisor, Heidi Hijikata who's the ITA Standards Liaison.

Heidi Hijikata: Okay. Thank you and good afternoon everyone. My name is Heidi Hijikata, ITA Standards Liaison for…

((Crosstalk))

Heidi Hijikata: I would like to welcome Dr. (Dornado)…

((Crosstalk))

Heidi Hijikata: …for our first (physical) video conference (unintelligible) US-Brazil Standards dialogue.

The Standards dialogue is part of the larger US-Brazil Commercial Dialogue launched by Secretary Gutierrez and Minister Furlan in June of this year.

There are four working groups under the framework of this Commercial Dialogue. There is (unintelligible) standard but there are three others. One on Intellectual Property, one on Business Facilitation, and one on Export Promotions.

This dialogue will take place through a series of video, video conferences, or VVCs and topics of interest to both countries will be discussed over several sessions.

Presentations may tackle general subjects such as each country's approach to regulations or focus on sector specific topic.

We hope this VVC experience will identify opportunities or challenges in standards development and regulatory processes, identify sectors for future collaboration non-standard and conformity assessment, and create an increased awareness of plans (and value) standardization activities to which the United States may be able to offer assistance.

In the longer term, we are hopeful that we will be able to strengthen mechanisms to achieve closer alignment of US and Brazilian standards and regulations in order to ensure that technical variance to trade did not impede the flow of products between our two markets.

If this agreeable to you, Dr. (Dornado), I would like to introduce the US Government representatives who will be speaking here today and then go around our room and allow our participants to introduce themselves, and then perhaps the Brazilian delegation can do the same.

Is that agreeable to you?

(Dornado): Yeah, thank you very much.

((Crosstalk))

(Dornado): We have some problem with this phone here.

((Crosstalk))

(Dornado): …I didn't quite understand what you are saying. I don't know about this (phone). Are you listening to me well, (unintelligible) well?

Heidi Hijikata: Yes, we hear you fine.

(Dornado): (Okay). Okay.

Heidi Hijikata: But you were having problems hearing us?

Man: Yup, definitely.

(Dornado): Now, I think (unintelligible).

Man: Okay.

Heidi Hijikata: We can…

((Crosstalk))

Man: Hello?

(Dornado): Hello?

Heidi Hijikata: We can…

((Crosstalk))

Man: Yeah.

(Dornado): Yeah.

((Crosstalk))

(Dornado): Please say something.

Heidi Hijikata: You want us to say something?

(Dornado): Yeah, just to…

Woman: See.

(Dornado): …to make this tuning off the phone. We have - no? Okay.

Hello?

Heidi Hijikata: Hello. Hello.

(Dornado): Okay.

Heidi Hijikata: Is that better?

Woman: Better?

(Dornado): Yeah, fine, fine. It's better now. Okay.

Heidi Hijikata: Okay.

(Dornado): So let me first say that it's really very, very nice for us to join with you in this first teleconference, video conference. I think this is really a very important test in the mutual understanding of the two countries. And also, you know, it's an important step in (unintelligible) to watch our two ministers as we (historically), I mean this (promotions go on).

And I would like to say that (unintelligible) Gutierrez and - Secretary Gutierrez (unintelligible) to learn. I'm expecting - looking forward for a successful implementation of this kind of dialogue.

And we all are very much (unintelligible) about this kind of form of (unintelligible) because the most important thing is to do understand us or mutual understanding and (unintelligible) and to keep way of communications is very important.

So I would like this to (unintelligible) to hold this presentation and we are - we'd like very much to hear from your people know, for the presentational representatives, and (unintelligible) also present out our people here.

Heidi Hijikata: Okay, oh just be in a minute.

All right. First, why don't we do introduction of our three US government speakers today.

To my immediate left, we have Mary Saunders who is the Chief of the Standards Services Division at the National Institute of Standards and Technology or NIST. And she will present a presentation on the US approach to regulation.

To Mary's left is another Mary, Mary McKiel who is the Standard Executive for the US Environmental Protection Agency.

And to Mary's left, or to the Mary's left, I should say, is Joe Mohorovic, Director with the US Consumer Products Safety Commission.

Mary McKiel and Joe will give some of their experience as they develop new technical regulations.

In addition to that we have, I don't know, about a dozen additional people around the room. We'd like to have them introduce themselves.

(Steven Bipes): I'm (Steven Bipes) at the American National Standards Body Institute.

(Jeff Grove): (Jeff Grove), AFCM International.

Ryan Hill: I'm Ryan Hill with the Information Technology Industry Council.

(Erin Waldron: (Erin Waldron) with Underwriters Laboratories

((Crosstalk))

Wayne Morris: …with the Association of Home Appliance Manufacturers.

Heidi Hijikata: Okay. Let's start in the corner. (At least one word).

Antonio Silva: (Unintelligible) (Silva) with the (unintelligible).

Woman: (Unintelligible).

(Bryan O'Byrne): (Bryan O'Byrne), Department of Commerce, (unintelligible).

(Dale Wright): (Dale Wright), Standards Liaison Office, Department of Commerce.

(Warren Strauss): (Warren Strauss), Monsanto Company.

Jennifer Stradtman: Okay.

I'm Jennifer Stradtman, Office of the ITA Standards Liaison.

Ileana Martinez: Ileana Martinez, NIST.

Paul Pavwoski: Paul Pavwoski, Office of ITA Standards Liaison.

Heidi Hijikata: And, Jennifer, I believe you have a few technical comments to make before we start.

Jennifer Stradtman: I would just note that on the - that there's a - well, actually also know there's few people on the phone.

How many people do we have on the phone, Paul?

Paul Pavwoski: There are about (12).

Jennifer Stradtman: Oh, good. Okay. I think we're going to hold off. We also have 12 additional participants on the phone, but due to time we're going to save that. You can see who they are using the transcript from the meeting.

So I just want us to note that if anyone's using the Webinar, what we're going to do is have the presentations first and then at the very end we'll take questions.

So if you have a question, what you're going to do is there's a chat capability…

Paul Pavwoski: Question and answer.

Jennifer Stradtman: Oh, a question and answer capability and you would type in your questions to Paul Pavwoski and he's going to relay that question. Okay?

(Dornado): Okay.

Heidi Hijikata: Got it.

(Dornado): Thank you very, thank you very much for - thank you for bringing (unintelligible) representative people to our video conference.

I would like to briefly introduce our Brazilian (sales) here. (Unintelligible) is the Director for (unintelligible). (Ricardo Cruz) is the Director for International Affairs. Alfredo Lobo, Director for Conformity Assessment and Quality.

And (unintelligible) support for the teleconference and legal mythology. MR (unintelligible) is the President of (unintelligible) Standard Association, as this ABNT is a very important body for support (unintelligible) and most of the regulations we try to tie that to introducing standards (unintelligible). (Unintelligible) also Director for ABNT. (Unintelligible), Director for Accreditation of (unintelligible), and other people, supporting people who are - would like to (unintelligible) there's different people who will represent (unintelligible) like to comment.

Heidi Hijikata: Great. Thank you very much for those introductions. And the next part of our agenda is I believe your presentation, Dr. (Dornado).

(Dornado): Okay.

We had some problem, technical problem I'm not able to put my overview here (unintelligible). If you have, please forward this overview that I have sent to you.

But first of all…

Heidi Hijikata: Dr. (Dornado)?

(Dornado): Yes.

Heidi Hijikata: I'm sorry to interrupt you. Could you talk into the phone? Our - the people on the Webinar can't hear you. Could you put the…

(Dornado): Can you hear me? No?

Heidi Hijikata: If you could also speak into the telephone.

(Dornado): Ah, okay.

Heidi Hijikata: Yes, perfect. Thank you.

Oh, now we can't hear you.

(Dornado): Just a moment there.

Heidi Hijikata: Okay.

(Dornado): We will make the phone connection.

Heidi Hijikata: Oh.

Coordinator: Please disconnect it.

(Dornado): It seems that we have two different channels.

Heidi Hijikata: We do.

(Dornado): Whereas by the telephone and the other is this (unintelligible) Internet.

Heidi Hijikata: It's a multi-media affair.

I do. Paul, why don't we set this…

((Crosstalk))

Heidi Hijikata: …I'll be able to say that.

Sorry, everybody. This is the first time we're doing this so…

Woman: Yes.

Heidi Hijikata: Those guys are taking care of this?

Everybody on the phone there making the document (unintelligible).

(Dornado): Just a moment.

((Crosstalk))

Heidi Hijikata: I don't know…

(Dornado): We had some problems, it's technical problems. I suppose perhaps we can discuss with the others (unintelligible) my presentation.

(How long will we use this?)

Ah, okay.

((Crosstalk))

(Dornado): How long are you going - how many minutes?

Okay, about three minutes. Okay.

Heidi Hijikata: So we just wait for three minutes though?

(Dornado): About three minutes.

((Crosstalk))

(Dornado): So it seems that there is only (unintelligible) in the internet, is that right?

Heidi Hijikata: Yes, correct.

(Dornado): Okay.

((Crosstalk))

(Dornado): So just to double check, I will do my presentation and then you will present the perspective of United States and then we will have some discussions and questions and comments. Is that right?

Heidi Hijikata: That was the original plan. If it makes more sense given the technical difficulties for us to do our regulatory presentation first, we'd be happy to do it that way.

(Dornado): Yeah.

Heidi Hijikata: Would you prefer that?

(Dornado): Yeah, okay. Sure.

Heidi Hijikata: Okay.

(Dornado): So I will present - I'll lead my presentation and then you'll make the presentation - you'll make two presentations, okay?

Heidi Hijikata: Well, there's actually three US speakers but in the interest of time…

(Dornado): (I see), okay.

Heidi Hijikata: Would you prefer that we start with one of the US presentations first while you're having…

(Dornado): Well, okay, that would be (worthy because I do have - I'll have response) .

Heidi Hijikata: Yeah, definitely.

(Dornado): Yeah, that's nice.

Heidi Hijikata: Okay. And then…

(Dornado): And then we'll have time to - is this working?

Man: Oh no.

(Dornado): Oh, no (unintelligible).

((Crosstalk))

Heidi Hijikata: Okay, let's go.

Man: Okay, good.

(Dornado): Okay.

So we are now set.

Heidi Hijikata: Okay, great. Okay.

(Dornado): Yes.

Man: Okay.

(Dornado): Okay.

So what I would like to comment in my presentation about technical (innovation) Brazil is first is to present a context discussion about the

regulatory situations of Brazil and briefly present the perspective of what is (unintelligible) is big context. And then I would like you to comment after or shortly about the number of or the most important regulatory (agents of) Brazil.

And also I will discuss later the most important regulatory practice that are underway in Brazil, so the way that we usually - the principles and the way that we usually (unintelligible) regulations of Brazil.

And also, and then we will end some comments about the regulations in (unintelligible) is a very important region here for Brazilians and then we try to harmonize our - most of our regulations especially the new ones (unintelligible). Okay.

So the first detail that I would like to present to you concerning the regulatory scheme of Brazil is to briefly present what we call the Quality Perception in Brazil. And Quality Perception in Brazil was formalized about 35 years ago. So we've started to push under the umbrella of our government big picture, the government decrees and so on.

And it is the basis especially business sector on three important concepts. One is the (Cymetra). (Cymetra) is a kind of system of all the bodies that are connected in some way with the Quality Perception in Brazil.

So it's a kind of very broad concept, is a system, the connection of all the bodies that are related to Quality Perception in Brazil.

And then (they changed) the most important part which is the (co-messages), the council. The council composes of about eight ministers and eight ministers of Brazil and about six or seven institutions representing important players in

the field of quality per person. For instance ABNT is a member of this council.

And this council (unintelligible) national council of mythology quality and standardization. This quality is responsible for making the big quality in Brazil and coordinating the big activity and the realm obviously of the quality including mythology, including conformity assessment and good standardization, any good (unintelligible) regulation. Okay?

And (unintelligible) us institution is the national mythology institution. But the (unintelligible) is a kind of a executive body of this council. So the (unintelligible) is a kind of operational body of Brazil system which council (unintelligible).

So this why we are here. So this is why we took the job of organizing these on behalf of Brazil. We are, so to say, besides being national mythology institute, (unintelligible) as I told you is executive body of (unintelligible). (Unintelligible) of this council. So this is very important to understand.

And I don't know if you have my picture in the Internet. So this would be the fourth slide. I have a picture of (Komet). And (Komet) is supported technically by a number of committees, about six technical committees -- Committees on mythology, committees on conformity assessment, committees on standardization. And they - one new committee that we have created about, that was - how long it was? That was three months ago?

Man: Yeah.

(Dornado): About three months ago, so it's a rather new committee which deals specifically with (unintelligible).

So we have a specific committee now dong articulation in the field of regulation in order to support (unintelligible). Why does (unintelligible)? It is because Brazil is a rather complex organization concerning the regulation activities.

In the next slide, I would like - I will show all the technical committees, also method that you can see in the Internet.

And in the following slide, so maybe there are six slides, I present very briefly what (unintelligible). As I told you, (unintelligible) is also is the executive secretary of (Komet) and is national mythology institute of Brazil (unintelligible) for United States.

And also (unintelligible) has different activities, just I connected (unintelligible), and that also helps (unintelligible), and his job also being executive secretary of (Komet). So we try to integrate all these activities.

So one activity is conformity assessment. So in this activity of conformity assessment, we produce schemes and arrangements, structure for conformity assessment program in Brazil.

Several conformity assessment programs are in the field of mandatory program. So they are connected regulations. So what we do, we take the regulations, we connect the regulations with the standards, we collect just in the practice of conformity assessment, and also we provide with our accreditation service of the necessary laboratory infrastructure to do this conformity assessment. So it’s a kind of (unintelligible).

Other activity (unintelligible) that already mentioned is just the accreditation part, the accreditation activity of. We met with (accreditor) of Brazil, official (accreditor) of Brazil. We have currently about 550 laboratories of testing and mythology laboratory and lots of other bodies that are, certification bodies that are credited, certification of people and so on.

So those accreditation activities, it's very important to say that they perform the conformity assessment which in turn supports the activity for regulation, for achieving implementation of the regulation activities in Brazil.

Not only in - (unintelligible) is also responsible for the legal mythology activity in Brazil which by itself is a very regulatory activity in all Brazil. We are connected with the state's institution that are dealing with rates and measurement.

But of course nowadays it's much more complex than just weight and measurement. It's more, let's see, a concern at which safety of people and health issues and so on, (unintelligible) instruments that are connected to the health like thermometers and sphygmomanometers and so on.

So this activity by itself is a regulatory. Needless to say that NIST is a very important regulatory agent with the issues, a lot of regulations. Not only in legal mythology but in conformity assessment issues that are connected with (basically professional procedures).

(Unintelligible) also the (inquiry points for) technical variations rate for the (unintelligible) organization. In this (unintelligible) also, we have a very flambeaus for regulatory activity in a sense that technical body (unintelligible) and no money connected through regulations that artificial to this (unintelligible).

So (unintelligible) is very much concerned with that, not only in for widening of the (inquiry) to the (well, big) organization, but also to helping to promote export of Brazil.

But, anyway, we have - if we do these, (unintelligible), we'll have a very much interaction system with the foreign partners.

And of course as I told, message is regulatory body.

The next slide that I'm presenting to you in the internet is some information of (national act), the regulatory and specifically in the general view of Brazil regulatory system.

So this is a very important information. Currently, we have in Brazil about - we have in Brazil 27 agencies that are issuing regulations. Some of these issues are very active issue and regulation like for instance, the minister of health is a very strong regulatory agent. The national surveillance institution, there's also some regulatory issues. I will show quickly the list of (unintelligible) regulatory body.

Some are very active, some are very important (unintelligible). I think that a lot of future conference of us will be with specific problem with specific agent. So there'll be specific people for those agents. Of course that will give some specific target that we will know - we'll then discuss later on.

And that itself is responsible for about…

((Crosstalk))

(Dornado): …29 measuring instruments, (unintelligible) measuring instruments regulated by (NIST). And we have 69 conformity assessment systems for (unintelligible). They go - that's right - yeah. Okay.

And I will - just to give you an idea of rather complex, and this is why we needed to be able (to do) this committee for regulatory body, (unintelligible). Committee for regulatory.

The number of regulatory body, I will just (unintelligible) very quickly.

Woman: Right.

(Dornado): Minister of Agriculture and Supply, this is a very important regulatory body in Brazil. And the Minister of Agriculture is also a very important body for grade - point grade. So I think this is one of the ministers or the regulations that in the future will be present here in our discussion. Okay.

Minister of Communication, communication also is issue that is obviously very much regulating in all the countries and - which impacts very much performance rate.

Minister of (unintelligible), the Minister of Defense, Minister of Education, Minister of Labor and Employment, Minister of Science of Technology, Minister of Environment, Minister of Transportation, Minister of Mines and Energy, Minister of Justice, Minister of Development Industry and Foreign Trade. This is our ministry. So (unintelligible) minister of Development Industry and Foreign Trade.

Minister for Health, as I told you, Minister for Health is also very important regulation for especially medical devices that according to Minister - to

Secretary Gutierrez is the important point of the discussion from the American side. So we can touch this - we can tackle this later on.

(Unintelligible) itself is also, as I told you, our regulation.

National Water Resource Agency, (now petrol), national gas and (unintelligible), and this is also a very important regulation in the field of oil, energy, fuels and so on.

Regulatory (unintelligible) of water, regulatory agency for electric sector, transportation agency, national health surveillance agent, so this also is very important agency as I've told you.

It's not the minister, so minister. So (unintelligible) health, we have two important regulations. One is a minister for health, is the ministry of health, and the other is the national surveillance agent we call (MVISA), (unintelligible).

So those two agencies are very important tools to the foreign trade also because it's deals with the health and they have different kinds of (report).

Next, the Brazilian Nuclear Energy Commission, the Brazilian State Agency, the National Telecommunications Agency -- this agency is also important and I think it would be interesting for you to know that because some of data related to communication is (given).

But also, as I've told you before in the case of health - in the case of telecommunication, there is one ministry, Minister of Telecommunication which also is regulation as I told you. And also this National Agency of

Telecommunication which is not connected to - tied to a specific government but it is indirectly connected (unintelligible).

There's also the (unintelligible) agency very similar to the USA. National Supplementary Healthcare Agency, and the Brazilian Institute for Environmental and Renewable Natural Resources is also one Asian connected to environment similar to Minister for Environment.

Okay. So I'm - I apologize for (unintelligible) statements concerning the (unintelligible) number of regulatory bodies in Brazil. But at least you have an impression of the complexity of Brazil. And this is this is also to enforce the need of (understanding), need of contact. And with different problems we need to approach different agencies. And of course there's different people and so on.

So this is the picture, the big picture of the situation. This is rather new I'd say for you. The implementation for regulatory agencies, the (sec) minister for instance is a kind of innovation in Brazil actually. It's less than I'd say ten years (unintelligible), so again, about 10 years, so it's rather new to this situation.

So but we have, of course, we have a rather sophisticated system but a complex system, and is a system which is under development (stage).

So then after this perhaps, the (unintelligible) agents, I'd like to comment briefly about some principles and some (unintelligible) in the regulation-making process as I told you before.

One principle is that whenever possible, we'd like to use Brazilian technical standards. The basis and the regulation can be more (effective) from the standard.

But we're trying to have upon existing standards, Brazilian standards, if there is no one standard, so we can do exceptionally basis on another standard just to create the specification. But in the meantime we asked the ABNT which is our national private body organization for standard which is also (unintelligible).

We asked ABNT to develop the system. And ABNT has a kind of fast-track system for developing standards which I need for the process of developing regulations.

So this system is rather new and is working well. There's standing between (unintelligible) regulatory agency in general and ABNT very well. So it's working properly.

And the second, whenever possible, we try to follow international (grant) and guidelines for (unintelligible) organization and so on. So we try to be more universal as possible.

Also we are most (unintelligible) regulation under program connected towards health and the user safety and the protection of environment. Environmental issues are very much concerned now in Brazil, so we are now paying attention to there, not only regulation agency but also the standard organizational, Brazilian standard organization.

And also we promote the participation of the interested parties. We do a lot of public consultation. And so (unintelligible) for all the stakeholders, for all the interested parties.

And also, we'd like to point again that whenever we need, we ask ABNT to develop (unintelligible) standard.

Another information that I think is worthwhile to note is some - this data is about regulatory practice because some highlight of regulatory practice -- (you can view that in) my forward - in my next slide -- when they use always of advisory technical commission composes by interested parties.

Also we are at more and more doing (unintelligible). We're doing (unintelligible) before starting the regulatory process.

This is not widespread completely in United States but it's a kind of trend now, so we are trying to be more and more open. As (a management), we are doing this way very often (unintelligible). And then I think this practice should become a more and more common to other regulatory agency, okay.

So after proposing regulations, we laid this regulation to our public consultation for a period of about 30 to 60 days. We used different channels to do this. Brazilian National (Logistic), (unintelligible), other regulatory bodies do basically the same thing. Okay.

So, then we do typically a project (unintelligible) listening also to what is going on. And after everything is set, we published the regulation (unintelligible) which is - so it became official. And after this publication, it's really mandatory, so it needs to be (forwarded) by other bodies. Okay.

And also besides that, we try to release as much as important - as much information as possible, okay, in order to make the people more understandable about the situation. Okay. Sometimes, there are usually concerning the proper understanding of...

((Crosstalk))

(Dornado): So I would like to end with some information concerning international aspects of regulations. And I'm closing my presentation.

So those are the last slides of my presentation.

One is that we maintain an agreement with several international form. For instance, the Technical (unintelligible) with the form of World Trade organization, and especially, we are connected to (Unintelligible).

So it's important to inform you that (unintelligible) is an important regional operator (unintelligible). So it is working and besides it's not so well structured as European community now, but we are progressing. We are - (unintelligible) is much younger than the European community so (unintelligible) and positive.

It's important to say this context of regulation that there are very - that a lot of the various committees in the (unintelligible), technical committees including, and there is one quality (super) group, technical (Super Group) 3 or Working Group 3 of (unintelligible) that deals specifically with technical regulations.

And what this group does is to harmonize the regulation. Not all the regulation of course, but the most important regulation that affects the multilateral commerce in (Unintelligible).

Especially, for instance, regulation in mythology, I mean, legal mythology conformity assessment of various kinds of (storage, food, automotive) (unintelligible).

And many of the standards are already (unintelligible) standards. And the regulatory (unintelligible), and then Argentina and then (unintelligible) and so on, tends to be harmonized. This is very good to avoid of course future technical variances.

So in the process of developing relations, we already tried to harmonize the standards. And those standards are taken out to development of harmonizing regulation in (Unintelligible).

So this is what I would like to say just to say. This is a very brief overview of their regulatory statutes in Brazil. I recognized that this could be rather complex and - but I would say that we are organizing more and more of the system.

And the system is becoming more and more efficient and then more and more coherent. And I think that we have already the basic mechanism to have I would say a centralized discussion of regulation (unintelligible).

So thank you very much for your attention. I would be delighted now to hear the status of United States concerning regulation.

Thank you very much.

Woman: Better.

Thank you very much Dr. (Dornado). That was very fascinating and we look forward to knowing more about your system (unintelligible).

Our first speaker is Mary Saunders with our National Institute of Standards and Technology or NIST.

Okay, we're moving the phones around.

Mary Saunders: Okay. Good afternoon.

I'm going to give you a high level overview of the regulatory system in the United Sates and then we'll have examples from the Environmental Protection Agency representative and also from the Consumer Product Safety Commission.

So your (unintelligible), Dr. (Dornado). I'll try to be as articulate as you were.

So Slide…

Briefly, I'll talk about the US regulatory approach, some examples of critical regulatory agencies, applicable US policy and then a few points on summary and conclusion.

Basically, the US Federal Register is the vehicle that the federal government and regulatory agencies, other agencies as well used to publish proposed technical regulations as well as final (text), and the code of federal regulation is the document in which you will find all regulations input.

The Web site - I've provided the Website at the end of the note on the Code of Federal Regulations where you can find that document online. There are 40

chapters on the Code of Federal Regulations. Some agencies have more than one chapter, so don't assume that we have 40 regulatory agencies. So we have some very active agencies in the US government at the federal level.

I'll speak briefly about legal mythology and the subset as we call it weights and measures in the Unites States which I know you are aware of some responsibilities of states government here in the US, not the federal government. Okay.

There is no single approach to regulation in the United States. Each agency has authorizing legislation. Some of that legislation goes back to many, many years through the 30s and even earlier had been amended over time. And for specific practice, you need to look to the implementing legislation that authorizes the particular agency.

And agencies follow that legislation as well as directions from our US Congress which is responsible for creating and passing laws to create, administer and to also enforce regulations very important activity here as well as in Brazil.

And regulatory (unintelligible) have to comply obviously with their implementing legislation and laws that are passed by Congress that apply to those specific agencies within the scope of authority, as well as executive orders that are issued by the White House regarding the process fro creating regulations.

As we have up here on one slide, examples of key regulatory. And this is - I noticed as Dr. (Dornado) was going through his presentation neglected to list are US Nuclear Regulatory Commission. But I think I was putting the presentation together late (unintelligible).

I think, beyond that though, I have hit most of the - all of the major regulatory agencies. If you consider, for example, the Department of transportation, not all elements of each of these departments will issue environmental regulations that have in accordance of law, but, as an example, the Department of Transportation includes the Federal Aviation Administration, the Federal Highway Administration, the National Highway Traffic Safety Administration which is responsible for vehicular safety, and other administrations that are part of that department that do issue regulations.

Department of Transportation also includes administrations that are not regulation issuing authorities.

The Food and Drug Administration is part of Department of Health and Human Services and issued regulations that cover food safety, safety for veterinary medicines, medical device safety and includes pharmaceuticals as well as biologics.

So, you have a range of activities incorporated, in particular, regulatory agencies.

The last two on the list, Occupational Safety and Health Administration and the Mine Safety and Health Administration are both part of the Department of Labor.

So the Department of Labor is responsible overall for labor issues in the United States. Only certain elements of that department have the responsibility issue regulation.

There are general - three general laws and one overarching executive order with some - one additional office of management and budget policy which address procedures for proposing and adapting regulations by agencies.

The three laws are the Administrative Procedures Act which is the basic requirement. I'll talk about each of these. The National Technology Transfer and Advancement Act of 1995 which has adopted by Congress about ten years ago, and the Trade Agreement Act of 1979 as amended with each of the - well state organization negotiations, and on executive order which covers regulatory planning and review. So I'll go briefly over each of those.

All right. As my colleagues in EPA and CPSC, you're all familiar the administrative procedures outside everything that we do. Not only regulatory activities; that covers every actions that an agency placed. So in this, we are not a regulatory agency, but we do issue notices about various activities and we are also subject to the Administrative Procedures Act.

With respect to regulations, the act ensures transparency on open rulemaking. It requires similar to the process in Brazil, publication of a notice of proposed rulemaking, how that notice is outlined and framed, may vary slightly depending on the agency issuing that proposed regulations. But there are a series of points that has to be covered in publication of a notice of the proposed rulemaking.

The opportunity of comment is a minimum of 30 days depending on the complexity of the proposed rule. That a comment period maybe as long as six months, if not - (that certainly seem) a six-month comment period, if not longer. But typically, 30, 60, 90 days is pretty much at the average.

And quite a bit of informal consultation has gone on prior to the publication of a formal proposed rule in some cases, quite a bit of input from other agencies that may have an interest in the proposed rule as well as, particularly, affected parties in the private sector.

The agencies are required to consider the comments that are received in the comment period and then in many ways in which the proposal is made available both over the Internet and in hardcopy and we now have a - an e-government Website which you can receive electronic comments on proposed rules as well.

Agencies are very careful about consideration of comments and must deal with a response to the comments in the next .notice of either a final rule. They may propose a notice for a second proposed rulemaking or they may go directly to a final rule, depending on the types of comments that are received.

But that final rule will contain a consideration of all the comments that will receive by the agencies and how they will dispose those.

I'd mentioned that agencies consult with other parts of the US government in areas where the scope of regulations are shared amongst different regulatory agencies.

Agencies - regulatory agencies also consult with NIST. NIST does a lot of measurement-related research in support of regulations for agencies.

We are- also cited several hundreds citations to NIST, other standard reference materials or NIST publications that you can find in the Code of Federal Regulations. And we are frequently asked to provide advice on measurement-related aspects of regulations.

Once the final rule is published in the Federal Register, it also becomes a part of the Code of Federal Regulations as I mentioned earlier.

Okay. The executive order which also is well-known by all regulatory agencies, it establishes procedures for planning by agencies for regulation and also for review of those regulations.

Again, agencies have to consider a ten-point list of different elements.

One of those is regulatory alternative. So when safe with the law that an agency is required to implement by Congress, the agency must look at all the alternatives by which they may accomplish the regulatory objective. And that includes, very importantly, if not, regulator.

If- there is a cost-benefit analysis that must be done by each agency, and there are very detailed procedures and examples given in the executive order as to how to conduct a cost-benefit analysis.

But if the cost of a particular approach to regulation outweighs the benefit, then the agency must choose another alternatives (and make sure) not to regulate. So they will also look at private sector alternatives in the context of rulemaking.

And impact assessment is very important. There are quite a few guide assessment to it, the impact assessment and risk assessment that agencies follow.

And I know for example that EPA has an entire cadre of risk assessment practices depending on the area of regulation as to (CPSC) and their agencies.

Each agency has to submit to our Office of Management and Budget which is part of the Executive Office of the President, the White House, a plan every six months. So they need to submit their plan for proposed regulations over the next six months including their objectives and their priority.

Now, they may not accomplish all - everything that's in the plan, but that the proposal has to go to OMB and OMB provides comment on that proposal.

This agency also has to submit individual proposed regulations to OMB for review, and they may receive advice from OMB regarding those regulations.

Typically, when the administration changes, the new administration looks a (host) on all regulatory proposal for a certain period of this time and so the new administration can develop their policies.

Okay. The National Technology Transfer and Advancement Act, which as I said was passed by Congress about ten years, is from the NIST perspective and for regulatory agencies a critical piece of legislation. It codified in law what had been a long-standing policy of the federal government to rely on voluntary consensus standard and regulation procurement and policy activities that Congress passed the law which made that the requirement for federal agencies to do that.

The law directs agencies to use voluntary standards to the extent that's practical, not only in regulation but also in procurement and in policy activity.

They are required to report to Congress annually, to OMB and to Congress the development of any government unique standards, when there is a relevant private sector standard that should - could be considered. And agencies are

also directed to participate in the development of voluntary consensus standards that are relevant to their needs.

The National Technology Transfer and Advancement Act is also known as Public Law 103114. And OMB, in particular, A119 is the much more detailed guidance that was issued by the Office of Management and Budget in 1998 to provide agencies with guidance as to how to implement the requirements of the law.

One of the provisions of the circular is the operation of the inter-agency committee on standards policy is (chaired) by the National Institute of Standard and Technology. I actually chair the inter-agency committee currently.

The members are all agencies of the executive branch that have standard-related activity. It may be regulatory. It may also be a procurement activity, Department of Defense, NASA, General Services Administration on major procurement agencies as is the Department of Homeland Security, in addition, agencies have policy activities that might rely on standards to all members of the committee. And the committee meets quarterly to consider issues that are relevant that need to be shared within the federal government.

The committee is also responsible for reporting to the Office of Management and Budget on the operation over the past year in terms of using policy on consensus standards.

There are clear goals and benefits to the government in United States of using voluntary consensus standard. The reason for the development of the policy and law in the United States is that to (unintelligible) some private sector

standards is considered to be beneficial to the government, improve the efficiency of government operation.

And now the US - the federal government is taking advantage of private sector technical expertise that are embodied in those many documents that are referenced in federal regulations.

A goal is to eliminate a cost to the government of developing government unique standards. A very important goal, decrease the cost of goods that are purchased by the government by referencing standards that are widely used in the private sector, and to minimize the burden of those that must comply with regulations by specifying standards that are widely used in the private sector in the market.

So for a broad range of purposes, eliminating cost to the government, promoting efficiency, promoting economic competition and furthering the policy of reliance on the private sector which is a very important priority in the United States that has been for many, many years.

We spent many hours in the inter-agency committee discussing what exactly using the standard means. And I won't go into a tremendous amount of detail. But I think it's important to note that (use) in our context in a regulation can mean incorporation of a voluntary standard in whole by reference or in part in a regulation.

And in fact, agencies, under the executive order on finding and review are directed specifically to look at only the parts of a voluntary standard that are directly relevant to what they need for regulation. So as the standard goes beyond what is needed to implement the regulations, that part of the standard should not be referenced in regulation. It should not be made mandatory.

It is an interesting point to me, we've have some recent discussions with the European Commission and their practice in Europe is that the commission must reference an entire document. It cannot reference a portion of a standard document as a reference standard under European legislation.

That is not the case in the United States and you'll find many references to just components (unintelligible), only the core elements which are necessary for regulation.

In particular many agencies, you'll see a lot of references to voluntary standards that are test methods, sampling procedures, or protocols, that is there's a wide range of references in those areas.

References to standards may also appear and do frequently appear in (unintelligible) guidance documents. They are not mandatory, but they are directions to the regulated community that this document is relevant to your compliance with this regulation.

It's a guidance, it's intended to assist regulated communities with complying with regulations. Those standards are not mandatory, but they are very important information for regulated companies.

And use, maybe determined in part by agencies enabling legislation. So, specific agencies may have a very specific definition of what it means to use a standard. They also have preferences for use and guidance versus use as a mandatory component. It's also influenced by the availability of relevant standards, and that's an issue in some areas.

Very simply titled, Four of our Trade Agreements Act of 1979 as amended implements the WTO Technical Barriers to Trade Agreement with all of its provisions.

So agencies are both subject to the two laws I mentioned previously as well as the Trade Agreements Act (unintelligible) as those laws reference standards all have to be considered by agencies.

And this operates the (inquiry) point under the WTO - for the WTO (CBC) agreements for the United States.

Regulatory agencies and I have listed most of those agencies, develop regulations in the United States, Congress passes laws and the agencies must develop the detailed regulations to implement those laws in the US within their scope of authority.

We have both law, the Administrative Procedures Act and policy, the Executive Order on regulatory planning and review, that establish procedures for agencies to develop regulations.

We have a very robust, open, and transparent system, and also it's a very practical system as well, which seeks to minimize the burden on the regulated community, as well as those that supply products and services to the government.

And finally, agencies are directed to follow those, the provisions of the Trade Act and the National Technology Transfer and Advancement Act regarding reliance on voluntary consensus standards where those are applicable.

And finally, as I mentioned at the outset of the presentation, our regulatory planning and review guidance from the White House and from the Office of Management and Budget directs agencies first to look at whether regulation is needed.

We have a very extensive market spacing in the United States with very active private sector organizations in many sectors, a lot of consumer information, product liability legislation, all of which combined in many cases, to mean that we rely on what is known as industry self-policing, which is that the industry deals with issues of leveling the playing field.

When it is necessary for the government to step in, agencies must consider the least cost and maximum benefit alternatives for regulation. They must conduct cost benefit analysis of various approaches, and sometimes these can be extensive.

(4:23)When (unintelligible) that a regulation is needed, and in many cases, standards are an appropriate tool to support that regulation. I mentioned various ways that agencies need standards.

We have a database of standard reference in the (unintelligible) federal regulations. At last count, there are more than 6000 (unintelligible) sector standards from a variety of different organizations, standards developing organizations that are incorporated by the reference into federal regulations.

Almost every agency on that list as well as the one I didn't mention, when it's a regulatory commission references exten - have extensive references to voluntary standards.

And agencies continue to introduce new procedures to improve their compliance with law and policy. So we have an ongoing process for sharing information across the government in terms of best practices and for working with the private sector very closely to ensure that the government needs are met through voluntary standards activities and that we have a strong partnership with information flowing both ways.

That's a very high level review. I help put here a couple of useful Web sites. There are others, but the first is a reference for the (code) federal regulations.

The second is the Web site which provides for Internet access, the comments on proposed regulations.

The third is a Web site that – when this operates which contains welcome information on the use of standards in all across the government, in both procurement and in regulation.

The database that I mentioned earlier is accessible there, as well as links to agency Web sites such EPA, CPSC, Department of Defense, and others. So there's quite a bit of information, all the relevant laws and policies are listed there as well.

So, I'd like to turn the podium over to my colleague, (Mary McHill) who's going to tell you a little about how EPA implements the law and policies that I've been talking about.

(Mary McHill): Thanks very much (Mary) for that presentation, and thank you all for the opportunity to talk with you about how we operate here in the US.

Next slide, please.

I'm going to build on what (Mary) had said and maybe add a few examples from the agency I work in, which is the US Environmental Protection Agency.

My role there is specifically as the standards executive, I'm on (Mary)'s committee. So, I do not participate in the development of regulations as such, but my job is to try to help the agency implement the National Technology Transfer and Advancement Act that (Mary) just talked about.

You could divide our activities within the agency into regulatory activities and voluntary programs.

Our regulatory activities of course, as (Mary) has just said, are based on the legal mandates passed by Congress that require the agency to write regulations and to ensure environmental health and safety in the United States.

They are enforced, some of them by us at the federal level, but by and large, the majority of regulations that we pass are enforced on a state level.

Now, one of the interesting things about that of course is that when we pass a regulation and we have the state enforce that regulation, the federal government, most of the time, does not provide resources for the state to enforce that regulation.

Sometimes that makes us not so popular with the state.

One of the reasons why the role of volunteering standards has really taken on a greater meaning for my agency and a number of other federal agencies as (Mary) was saying, cost effectiveness is a real issue. And on - in our

regulatory activities, we are to incorporate voluntary consensus standards in accordance with the law.

Our voluntary programs are largely partnership-type programs, where we partner up with industry and other non-government organizations to try to accomplish large goals in the area such as pollution prevention.

I know that that's something that's of great interest in Brazil. I've had the opportunity to work with a number of people in Brazil on pollution preventing mechanisms and policies. So, I think that that's something both our countries can be very proud of in working towards having pollution not be created in the first place.

That will certainly help reduce the number of regulations that are ultimately needed.

Incentive programs form another aspect of our voluntary program. And in both of these types of voluntary program, we also try to use and do use voluntary consensus standards as applicable.

Next slide please.

Our law - our regulatory action to DTA, laws for environment health and safety, a couple of examples is the laws that we implement are the Toxic Control Substances Act, the Resource Conservation and Recovery Act, the Clean Air Act, the Clean Water Act. But those are only a few.

It is important I think to point out that sometimes when Congress writes an Act, it leaves a fairly broad opening for the agency to interpret how we're going to regulate and what kinds of regulations and measures we'll use.

Some of the laws, however, in the legal language itself, are fairly constrictive on EPA. And the laws themselves will tell EPA exactly how to regulate and what to say and what to measure.

So we have a variety - we have different levels of ability within regulation writing ourselves.

The law on standards and conformity assessments, the National Technology Transfer and Advancement Act, which you've heard (Mary) talk about in the trade agreement, all of these are things that we are to consider in our regulatory actions.

Next slide, please.

If you wanted a kind of diagram of how we go about making the decision to regulate, this would be pretty good. All of the things that you see there, some of which (Mary) talked about, are necessary for us to consider.

First of all, we have to have a legal mandate which is requiring us or giving us authority to regulate in a particular area. Then, we have to think about, how we do it. Will it be easy to implement (in the court)? What are the cost analysis, the benefit analysis? Is there flexibility allowed? How can we build that in?

Is it a timely regulation? Is it something that needs to be done very quickly? Is it an urgent problem that needs to be addressed? What are the trade related obligations that we can see or imagine in doing the regulations? Certainly, we have to have very good sound analysis in all of this and transparency.

One of the things to keep in mind while we are writing these regulations relative to trade agreements is in the final analysis, EPA has the responsibility to protect the health and environment here in the United States. So that's paramount.

If we have an authority and we need to pass the regulation, the paramount responsibility to protect the health and environment can sometimes weigh these things like cost benefit analysis one way or the other.

If there's a huge need to protect because there's a big problem.

Back in the 1970s, we had a lot of difficulties here with water pollution in a number of areas. We had a river in Ohio that was actually on fire. So, it was an urgent need to pass regulation and the cost benefit analysis was not a lengthy one. We had to get out there and regulate.

Next slide, please.

But voluntary standards have become increasingly important to the agency in the way that we regulate. There are some examples in front of you of where we have regulations, and we have made extensive use of voluntary standards from a variety of standards development organizations.

Refrigeration, recovery, equipment, methods for examining water, and waste water E. coli, permeation of liners for underground storage tanks, measurement system, and there's just hundreds and hundreds more examples.

In all of these or most of these, what we have done is what (Mary) just described, we cite a standard and we use it as the primary test method to tell the regulated community in order to be conformance with the regulatory limits

of this regulation, here are the testing parameters that you should use so that you can have confidence you are meeting the intentions of the regulation.

Next slide, please.

Voluntary and incentive programs in EPA of course, are not enforceable. They are not written as regulations. But they are drawn from the mandate that government govern the agency.

I mentioned pollution prevention. You all may be familiar already with Energy Star Program, which seems to be gaining worldwide and environmental management systems. I know that a number of people from your country have been involved in the development of the ISO 14000 Standards.

These kinds of programs -- next slide please -- also make use of voluntary consensus standards. What the agency will do, for example, is to get together with our stakeholder, our industry and our communities, our non government organizations, our academics etcetera, and put together a program with something like best practice guide in federal energy challenge for green building or product manufacturing (and use).

Energy is the big issue right now.

Instead of writing regulations for all elements of that, the agencies will put together programs to offer incentives to organizations who meet certain criteria, criteria that is based on voluntary standards and guidelines that the stakeholders and EPA have put together.

The latest one is the recycling of electronic products which is done directly from an IEEE standard that is just newly been passed.

I would like to say at this point that one of the most critical things for our agency in doing the regulatory and the voluntary work we do, where we use standards, is our reliance on our relationship with the American National Standards Institute -- which is our national body -- and likewise, with a major standards development organization here in the United States that are recognized internationally, among them, ASTM International, UL, and a number of others.

They are key to our consideration in which standards were used in our program.

Next slide.

Giving you then system resources that you might want to look at, government regulations, current laws, the test methods that the agency has developed -- next slide -- and some standards related resources.

And we also are glad to answer any questions that provide anymore resources as you might like them.

Thank you for the opportunity.

And now, I'd like to turn the program over to my colleagues in the Consumer Product Safety Commission.

Joe Mohorovic: (Hello there).

Thank you. Thank you, (Mary).

My name is Joe Mohorovic. I'm the Director of International Program for the Consumer Product Safety Commission. And the purpose of my presentation today is to describe very briefly the way by which the CPSC promulgates a technical regulation.

But first -- I think this is the very last slide actually. By way of introduction, the CPSC is an independent federal agency. We were established in 1973 and we're responsible for the consumer product safety functions in the federal government.

Next.

Purpose is to protect the public against unreasonable risk of injuries associated with consumer products. We carry out our mission five ways. We promulgate regulation, we recall defective products, we administer civil and criminal penalties, we also participate in the development of consensus voluntary standards, as well as developing information and educational programs for consumers.

By virtue of product safety standards, the regulatory process can be started one of two ways, either by a vote of the commission or upon receipt of a petition from an interested party.

However, our – by act, the Consumer Product Safety Act, which is our enabling legislation, also acknowledges the very important role that voluntary private sector consensus standards play to provide an adequate level of protection for the American consumer.

The first ways that a technical regulation can be promulgated is from anybody in the United States can petition the agency in writing to promulgate a technical regulation.

The staff of the consumer product base, the commission will review the petition and prepare recommendations which could possibly be to grant, deny or defer action. And if the commission voted to grant the petition that would begin the technical rulemaking process by sufficient.

However, the commission also establishes its own set of priorities. So just merely by a vote, the commission itself can begin the promulgation of the technical regulation.

I got to hold on to - now (unintelligible) that there's (CDC) at (Paul) since if we run out of time.

Man: (Unintelligible).

((Crosstalk))

Man: Shall I be - shall I continue for the Webinar?

Woman: Yeah. I'll - please don't - I think they're on the Webinar as well.

Man: Okay. Would you mind taking the wheel for me then, (Illiana), to advance the slide?

(Illiana): With pleasure.

Man: Thank you.

(Illiana): (Unintelligible).

Man: I beg your - I just mailed to (unintelligible) (screen).

((Crosstalk))

Woman: (Yeah).

((Crosstalk))

Man: (Unintelligible), we just recognized that there's a hold on the screen of the (DVC). They were investigating that, but we'll continue with the presentation and the slideshow for your purposes of the Webinar.

Next slide, please.

What makes our agency unique in very many ways as opposed to what (Mary) described for the rest of the federal government is our agency has a three-step as opposed to just merely two-step rulemaking process for the promulgation of the technical regulation. That is before we go to a notice of proposed regulation, we actually have to do an advanced notice of proposed regulation.

And at that point, the public is given the opportunity to comment and the agency - if the commission voted to promulgate the rule, they would supply that public notice.

Next slide, (please).

After the comment is made available to the public, the staff does a review of those comments and the commission may hold public meeting.

Woman: (Unintelligible).

Man: Keep continuing.

Woman: (Unintelligible) how this could find out if it's still on the Webinar?

Man: Very well.

Woman: (To me that…)?

((Crosstalk))

Man: Well, on the proposed (rule state), the commission would then vote to each of the proposed standard for comment. A much more significant level of detail is required at this point including the actual proposed mandatory standards, preliminary review of costs and benefits and all the reasonable alternatives must be investigated as well.

Finally, the reasoning why a voluntary standard to adequately address the hazard needs to be explained in the notice - in the NPR, the notice of proposed rulemaking.

Woman: (Uh-huh).

Man: Then again, after the published notice, the public has the opportunity to comment on that notice of proposed rulemaking. The staff analyzes the

comments and refers them back to the commission for proposed votes to move forward.

As well there are certain expressed finding that must be provided, which include the finding of the mandatory standard is necessary to reduce or eliminate the unreasonable risk.

That is the least burdensome alternative and that's the benefit there, reasonable cost to be - reasonable cost to the benefits and that there is - if there is a voluntary standard that exist that it does not adequately reduce the risk or it is not likely to be complied with substantially.

Finally, the commission could then vote to which of the final technical regulation and that rule is published in the federal register. It is effective date can be 30 days at no shorter than 30 days after the publication (absence with cause).

I've also provided on the last - the second to last slide just for your own review, a list of the rules that the agency is considering promulgating that was last published in the semiannual regulatory agenda in April of 2006. And that is the conclusion of my presentation to drive the process for the promulgation of a technical regulation. Thank you.

Woman: You're welcome (unintelligible).

Woman: Thank you (Mary) and (Joseph) for that presentation.

Can we still have the folks in Brazil on the line?

Woman: (Unintelligible).

Woman: (Unintelligible)

Woman: No, they have to (unintelligible).

Man: We are now without image, so people are trying to fix what's going on.

Woman: Yeah.

((Crosstalk))

Man: We are listening to you perfectly clear.

((Crosstalk))

Woman: (Unintelligible).

Man: Yeah.

Woman: (Unintelligible).

((Crosstalk))

Woman: Yeah.

((Crosstalk))

Man: Okay. (We have like)…

((Crosstalk))

Man: …(pieces) again.

Woman: Okay, great. Sorry for that technical glitch, but hopefully, you know, we can (unintelligible).

We're a little bit short of time, but I would like to open this up for some questions and answers of our speakers today to help (unintelligible) just ask them (unintelligible) if you have any questions that you have for any of our three speakers.

Coordinator: If you have a question, please press star-1. You'll be prompt to record your first and last name.

(Unintelligible).

Man: Hello.

Woman: Yes. Are there any speakers from those in the (DVC) room in Brazil?

Coordinator: (DVC) - I'm sorry they disconnected.

Woman: They disconnect?

Woman: What?

((Crosstalk))

Woman: They're still in the (DVC) (unintelligible).

((Crosstalk))

Woman: Dr. (Jerry) (unintelligible), do you have any questions from your side there?

(Jerry): Well, first of all, (I've learned) (unintelligible) they're very nice and comprehensive presentation (unintelligible) yourself of the arrangement (unintelligible) it's very nice.

((Crosstalk))

(Jerry): I just like to mention some few remarks that - first of all, we also have in Brazil some (unintelligible), to our tools, you know, from the difference, (unintelligible) industries in Brazil.

What we are trying to do in the committee is now for arrangement is to bring more (mobility) in this (unintelligible) more standardization, your practice of it. We are also trying to build a standard for guide for wound regulation practice (unintelligible). One question, (unintelligible) we have a similar (unintelligible) broad spectrum guide for all the regulatory industry (unintelligible) who have guidelines for good regulation practice for all the regulatory industries in (the United States). We'll be very (unintelligible) this is one (unintelligible)…

((Crosstalk))

(Jerry): Another question is the (unintelligible) in the United States, you have very strong relation in (unintelligible), what about the (unintelligible) place between (unintelligible) that regulates - how could they connected - harmonize and then - and so on. So I don't know is there (unintelligible) myself was right to make the comment and question, so (unintelligible).

Woman: (Thank you). But then again, (in the) general policies require the results (unintelligible).

Woman: Okay. Can I - (Mary), before we get too far…

((Crosstalk))

Woman: Let me take your questions in order…

((Crosstalk))

Woman: The executive order that I mentioned then, we can provide you a direct link to that order. And it's a regulatory planning and review is (unintelligible) guide to good regulatory practice for the US government, so that's - which indicate the aspects that it must consider.

Man: For this is really…

((Crosstalk))

Man: In some of our (unintelligible)…

((Crosstalk))

Man: …(to repeat).

Woman: The executive order that I summarized very briefly is (12866), which is called regulatory planning and review issued by the office of management…

Man: Okay.

Woman …and budget is our guide to good regulatory practice.

Man: Okay, thank you.

((Crosstalk))

Woman: With respect to your question about the state versus the federal government, under the US constitution, what is - anything that is not derived by the federal government is reserved to the state. In most cases, (unintelligible) mentioned that the federal regulatory agency the authority to issue regulation rest primarily at the federal level.

You noted that my colleagues from (EPA) mentioned that (EPA) issues federal regulations covering environmental areas under their scope of authority under the laws that they implement. Enforcement is done at the state level.

In the area of workplace safety, the occupational safety and health administration issues regulations. Enforcement is done at the state level.

In agriculture, the US Department of Agriculture and the Food and Drug Administration will issue regulations and particularly in agriculture not process through its enforcement is - that is at state level, they are - for example, in the State of Florida, in the State of Pennsylvania, in the State of California each maintain specific regulations that affect agricultural product within their orders.

In most cases with a few exceptions, workplace safety enforcement, specific aspects of agriculture and construction, regulation is done at the federal level.

Regulation of building and construction is under the state and local level in the United States.

And I mentioned the fourth example, ways and measure, packages, quantity, sizing, labeling, identity of product in commerce in the states, gas - measure - pumping gasoline, grain - specific other products is the responsibility of the state regulators with support from the Federal government.

We (unintelligible) the inquiry points under the technical (unintelligible) track those federal regulations. We also review state registers to identify any proposed regulations at the state level that might have international trade implications. There are very, very few that are identified that have international trade implications.

What was the last question?

((Crosstalk))

Woman: Oh I'm sorry.

((Crosstalk))

Woman: The last question was I thank for that because I forgot to mention the fact that under the National Technology Transfer and Advancement Act (unintelligible) are directly to coordinate with federal agencies on conformity assessment activities within the federal government and between the government and the private sector.

(The direct) (unintelligible) provided by the law is not quite as strict on the conformity assessment side as it is on the standard side we issued in 2000. We

have issued in the years 2000 guidance for federal agencies conducting conformity assessment activities, and that guidance is still in effect. I can send you the link to that document. It basically calls out principles that agencies could just consider in either developing or amending conformity assessment programs to support regulatory activities.

We do not have a law in United States that mandates accreditation of laboratories, of product certifiers, of personnel certifiers. We do have very active programs, most of them in the private sector in the laboratory accreditation area, in the accreditation of product certification and accreditation of personnel certification. We have one federal government program, the national voluntary laboratory accreditation program.

And laboratory accreditation is specified by particular federal agencies when that is necessary to meet their regulatory intent. We have many examples of specific programs that mandate accredited laboratories.

Woman: With (unintelligible)?

Woman: Oh, it's well within - there is - yeah. There are a mixture of - in some cases laws, not recently but from the 1970s under (the asbestos) - the acts governing asbestos, we are directed to (accredit laboratories) with tests asbestos meet (EPA) requirements under regulations. And there are agency programs that Energy Star, for example, which is a voluntary program does specify the use of accredited laboratories.

So a variety of programs, we do not have a comprehensive law that mandates their particular approach to conformity assessment. That is that decision is left to the individual agencies implementing laws and administering regulations.

(Jerry): And so, thank you very much.

Woman: You're welcome.

(Jerry): So what is the one question that (unintelligible) you have mentioned that there are in some cases (incentive) through the compliance to which there are voluntary standards (unintelligible) as well as in the presentation of the (unintelligible).

I don't know if I - if somewhat (unintelligible) - you guys understand correctly that in certain case you have incentive process (compliance) who is voluntary (unintelligible) not (unintelligible), is that right? (Unintelligible) understand correctly?

Woman: Basically (you did). The incentives are not for achieving required regulatory conformance. The incentive programs, most of them, are for voluntary programs, but it give you an example.

Can you hear me okay on this?

(Jerry): Yes, yes…

((Crosstalk))

Woman: Okay.

We promote in our voluntary program the use of environmental management system as a way to encourage and foster the prevention of pollution. So for organizations and federal agencies in states - well, particularly for the private sector that wished to sign up to, sign on the dotted line with (EPA) that they

will meet the voluntary program requirements or guidelines then we can offer to them something like a reduction (unintelligible) in the number of inspections that we will do at specified plants.

It's very strictly laid out and if you could imagine, our attorneys are, you know, right on top of everything. But there's an incentive for organizations to incorporate voluntarily environmental management system in order to, you know, potentially reduce the number of inspections that they have to go through.

Now, there's caveat to this of course because the agency is always wanting to make sure we do not lessen our regulation or give up any of our authority, but we have had a lot of success with getting small businesses and even some municipalities to sign up to voluntary programs and over the course of time, the state who usually provide, you know, the enforcement on regulation, they're starting to get the idea that if organizations have a robust environmental management system in place, they are less likely to be problematic organizations, with regard to state or federal environmental regulation.

So it's proven it to be an encouragement to regulators to think about how we might use our resources in the best way so that we can put our attention on those organizations that needs more attention than others.

Does that address your question?

(Jerry): Yeah. Thank you very much. It's very (unintelligible). And I thought that we use this for something like (unintelligible) reduction.

Woman: I know.

((Crosstalk))

(Jerry): …more intelligent. Okay.

Woman: I wish I could.

Woman: (Unintelligible).

Woman: Thank you for those questions. Are there any questions there on the US side?

Woman: (Unintelligible).

((Crosstalk))

Woman: I have it (unintelligible) out if you have any formal planning for your regulatory process to either individually by agency or in the (unintelligible) in (Metro), and are those plans for future regulations, are they publicly available (somewhat)?

(Jerry): Yeah, (unintelligible) thank you for the question.

As I told you, we are in the process of (unintelligible) this. Is (unintelligible) which I think with all the regulatory bodies. The average (unintelligible) has (unintelligible) difference and in the - we almost (unintelligible) those regulatory bodies. We look forward to have the (unintelligible). But that was, that (unintelligible) comments off of (unintelligible) procedures inside a method of the regulatory body okay, thank you.

Well, they, as (unintelligible) said, we have a plan (unintelligible). And every agency asks, (is it our plan)? Today, we'll have discussions in the (unintelligible) (a guide) to be followed by (eight) cases. As (we disclose) plans, (unintelligible). So, we're having discussions today and a (plan) prevent (unintelligible) (and to set the priorities in relation to) (unintelligible).

Yes, (unintelligible) it has (unintelligible). (Perhaps that is a plan) (unintelligible) in relations to some of the benefits, procedures and (unintelligible).

Okay?

Woman: Thank you.

I have another question.

Have you heard there is a very strong link in the United States between the laws that our Congress passes and what agencies can do? Is this the same in Brazil or do the regulatory agencies have more flexibility to regulate in areas where they feel there is a need without specific and strong mandate or (instructions) from the Brazilian Congress?

Man: This is a difficult question to answer because it's difficult to specify (unintelligible) where you say more (unintelligible) and things like - But I would say to you, there's a - I don't want a situation in the United States where (unintelligible) to Brazil.

But I will say that, of course, we need to get - to comply the laws of the Congress and also the decrees that are issued by Government, the bills that are issued by the Government.

But we have a little more flexibility because we have to (unintelligible) with the (unintelligible) of, as I mentioned to you, (unintelligible).

And sometimes, as the relationship between one body - organization (unintelligible), we can decide by ourselves and we can (unintelligible) between two -- well, I'm sorry -- even three (unintelligible).

Like for instance, (unintelligible) the Ministry of Agriculture (unintelligible). So we can put - (unintelligible) discuss the availability of regulations and - (because) the best organization would (unintelligible) such a (unintelligible) (regulation) to (unintelligible) regulate. So, (unintelligible) are sometimes (unintelligible) some standard or some resolution we say. Some resolution (that empowers) the regulatory body to do (unintelligible).

(To) (unintelligible) is a really good thing (in this world). So, to make resolution of those kind of some of - those questions. So (unintelligible), you can go to (unintelligible) and then you can (unintelligible) about that. So again, you can have (unintelligible) and (unintelligible) would say, well, that you can (unintelligible) and so and so and so. So I think this (country is very good).

And by the way, we will have a special council in the United States.

Woman: (Unintelligible).

Woman: Well, first of all, thank you for your answer.

I don't think we have anything comparable to (Metro) in the United States…

Woman: No, uh-uh.

Woman: …since there's no grouping of regulatory agencies, (unintelligible) that I (unintelligible).

Woman: (That's the general purpose).

Woman: (Unintelligible), yeah.

((Crosstalk))

Woman: Do you think it's an (unintelligible)?

((Crosstalk))

Woman: Well, right.

Woman: Yeah.

Woman: I mean, there's a grouping of agencies to talk about use of voluntary standards and regulation of procurement. And there is an office, as what (Joe) mentioned, in the Office of Management and Budget, which is that office is responsible for oversight of all regulatory agency activities.

They probably do periodically call the agency representatives together on a specific issue. But I don't think they (unintelligible) to talk about regulatory (approaches), but we have an Office of Management and Budget and one of the offices in that organization is responsible for regulatory oversight across the Government.

Woman: Do they (unintelligible)?

((Crosstalk))

Woman: Oh.

Man: (Unintelligible)

Woman: Yeah.

Man: Oh…

Woman: Okay.

Man: …(unintelligible). (Unintelligible).

((Crosstalk))

Man: So (unintelligible).

Woman: Does anybody have any question?

Woman: I have one last question.

Woman: Excellent.

Woman: Hi, I have one last question.

One question that frequently comes into the Department of Commerce is, what is the relation between Brazil and MERCUSOR when you're developing a technical regulation? Where is the real meaningful opportunity for input?

We understand that once there's the MERCUSOR regulation that's already kind of agreed to by the countries of MERCUSOR. So is there a way for US interests to (comment) into MERCUSOR?

Man: We would like to comment about, (you know), the specific - yeah?

Man: (Unintelligible).

Woman: (Oh, I am).

Man: Yeah. And I'm afraid it's not possible because there is no public consultation, just internal consultation. This is - it's only for member states.

Man: Yeah.

Man: By the way, do you have in the (unintelligible) form a kind of (amortization) (unintelligible)?

Woman: No.

Woman: None.

Man: Do we have it in the (unintelligible)?

Woman: Oh. Oh, NAFT?

Woman: For NAFTA?

Woman: For NAFTA?

Woman: Yes - no, not at all.

Man: Yes. NAFTA, yes.

Woman: No, we don't have a similar mechanism.

Man: No? Yeah.

This is just in internal, okay?. And I have told you - as I've told you before, this is just (being contested). The number of - just to give you an idea, I have some (unintelligible).

By the way, in the…

Woman: Yeah.

Man: …in (unintelligible) put some links, some references for people that want to - more information. But (unintelligible) (I don't know if there has been) - this is (unintelligible). What's the number of…

Woman: (Unintelligible).

Man: …(I talked to) a number of (unintelligible) and the MERCUSOR (unintelligible).

So (we will have to harmonize) the 464 regulations under MERCUSOR. So, 464 regulations, we already (unintelligible) of MERCUSOR.

Woman: A quick question and follow-up on - I guess I'm wondering then, as you adopt the MERCUSOR regulations, do you ever manipulate or change what comes out of MERCUSOR as a result of comments that you might receive in Brazil?

Man: Oh, I think so your - the question is (how we'd want to) - after the NAFTA's deliberation, so we have a …

Woman: NAFTA (unintelligible).

Man: …the possibility of adding some comments in Brazil. But this is - (yes, of course) they want. So we work on harmonization after the (unintelligible) inside Brazil, okay? Yeah.

Yeah, so the (unintelligible) harmonization is after this internal discussion, okay? So there's a lot of

Woman: Okay…

Man: …so (unintelligible) process in (unintelligible).

But of course, let met tell you - let me add that this is a very, very iterative process. So, if after discussion on the level or MERCUSOR, something was (borrowed) from the original one that will have (unintelligible), then we go against the MERCUSOR. So, with the (unintelligible) both - and you - we can have several done.

This is the same way you develop (interventional incentives), okay? So it's a similar of process of developing (unintelligible), but the difference that you are talking about the regulatory (process).

Woman: Thank you.

I think that many (unintelligible) the Department of Commerce would like to see a better opportunity for all interested parties to participate in that process or to be able to have some type of (comment) to the country because you are (notifying) those regulations to the WTO but there's not a real opportunity then for us to provide (comments). And that's where we - across industries, we see that concern come in.

Man: Yeah, I think …

Woman: So I don't know if there's (unintelligible).

Man: …that a good (unintelligible). I think that by this kind of a dialogue, we can discuss. I think this is the most aspect of a dialogue, a formal dialogue that we have or has been started between the Department or Commerce and (unintelligible) of development.

So we can discuss these things and we can (draw) different qualifications (in) the development of this (unintelligible), just knowing what's going on and what are the available opportunities to develop different standards.

And I think that for the next (unintelligible) in this, you know, war, we get the (unintelligible) the different issues. There may be opportunities for both of the countries either in developing new (standards) or in changing or reviewing the existing standards.

Or also, in the application of their (standard of their regulation) - the application of the regulations, because in the application of regulation, especially the framing of (components), the systems of a (unintelligible) - in framing of a system of, I'll say, the (unintelligible) of the process, we can bring down a lot of technical (unintelligible).

It's not only the regulations, it's not only (what's the standard) but how do we (implement) the regulations (exactly). So, performance assessment and the specific steps that (is a part of performance assessment certification). This is a big opportunity and this is important in this kind of dialogue.

I think that we can, for the next conferences that we have, target some of the specific issues that that we want to (unintelligible) and we would like to give (unintelligible) more lubricating, (so to speak), action between the two countries..

I know that, for instance, Secretary (unintelligible) is very much concerned with issues concerned with medical device (unintelligible). Well, this is an issue where human relations apply in the interpretation of the regulation. And as I've told you, the way to (fulfill) the regulation is specifically how to assemble a performance assessment (unintelligible) (in view of) (unintelligible). (Unintelligible) we can discuss (on this end).

But anyway, returning to your comment, to your question. We think it's very appropriate for the discussion we have. I think there are some - there's (occasional) - we can have a discussion the during the development of the regulation. I don't see any difficulty in doing that.

It depends on preparing an agenda of (common interests) between the two sides. So, if we have an agenda of (common interests) in developing regulation in both of the countries, then we can discuss doing the development of the regulations, okay?

As we are discussing now, (you know, this) (unintelligible)…

Woman: Well, we certainly (unintelligible) your answers seem candid and open.

Man: (Yeah.

Woman: (Uh-huh).

Thank you.

I think that is a good conclusion for today's activity. We've had a very fruitful discussion I think. And I understand the next (CVC) will be on October 18 at this same time.

Before we leave, are there any last (comments on our side)?

I certainly would like to (thank the staff involved in putting) this together both here at the Department and again in (Metro). I think you did a great job (unintelligible). So, I thank you for that.

Man: (Unintelligible).

((Crosstalk))

Woman: Okay.

((Crosstalk))

Woman: (Unintelligible) thank you.

Woman: And with that, do you have any final concluding remarks?

Man: Well, first of all, I would like to thank you also very much for all the inputs (unintelligible). We're going to (unintelligible). So - but I think joint effort was very fruitful I think. And (unintelligible) (we are perfecting the) (unintelligible) of communicating better. And we (thank you for) targeting the most important issues that will be very much important for our future.

I would like to also say thanks for my fellow colleagues from Brazil, and (Metro), from (unintelligible) and other agencies that are right here. And we look forward for our next conference.

In the meantime, I would invite you all that we can communicate by mail. And then, lastly, (unintelligible) communicate by mail about the possible agenda as (unintelligible) because of issues that could be developed together (unintelligible) that we can exchange idea during the development of regulations. And also not only the development of (unintelligible) but just concerning the implementing of (unintelligible). How do you assess the - how do I performance of (unintelligible)? What we also observe in Brazilian and in other countries is that one thing is the regulation; the other thing, is there a way to regulate (this that is demonstrated to be) (unintelligible)? And this is I'm - this is why I'm referring to these themes of performance assessment (unintelligible).

But we are open to all the - to work together not only in the field of - in the moment of developing standards but also in the implementation with performance assessment. And we - (that's why want to - as we think together about one agenda about this old issue.

And finally, I would like again to thank (Roberta Martin), to express my deep satisfaction about the work that we just concluded today. This, as I've told you, is just beginning. And (unintelligible) and then, thank you for all.

Thank you.

Woman: (Open the) (unintelligible).

Woman: Thank you.

Woman: Okay, thank you.

((Crosstalk))

Man: Thank you.

((Crosstalk))

Woman: Bye-bye.

((Crosstalk))

Woman: Oh, (it's great)

Woman: There you go.

Man: Yeah.

Woman: We've got to (unintelligible).

((Crosstalk))

Woman: Yeah.

((Crosstalk))

END